UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 0:24-60522-CIV-DIMITROULEAS/HUNT

KOVADIS PALMER,

Plaintiff,

vs.

PHILIP MORRIS INTERNATIONAL INC.,
and SWEDISH MATCH NORTH AMERICA LLC,

Defendants.

DEFENDANT SWEDISH MATCH NORTH AMERICA LLC'S
REPLY IN SUPPORT OF ITS MOTION TO DISMISS

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I. INTRODUCTION

Plaintiff Kovadis Palmer's Opposition—a near word-for-word copy of the opposition filed in *Kelly v. Philip Morris International*, No. 0:24-60437-CIV (Dkt. 39)—similarly fails to show that his Complaint sets forth any plausible basis for relief. Just as in *Kelly*, Plaintiff's failure-to-warn, design-defect, negligence, and fraud claims fail as a matter of law. As an initial matter, Plaintiff's claims based on ZYN's labeling and packaging are preempted by the Tobacco Control Act and should be dismissed with prejudice. Yet even setting aside preemption, all of Plaintiff's claims must be dismissed for failure to state a claim. The Complaint largely recites legal standards and offers unsupported conclusions, which are not entitled to an assumption of truth, while the few facts in the Complaint speak for themselves: ZYN provides a prominent warning that it contains nicotine, an addictive chemical, *e.g.*, Compl. ¶¶ 2–3; ZYN's label accurately discloses the amount of nicotine in each pouch, *id.* ¶¶ 2, 5; ZYN is an age-restricted product with flavors designed to appeal to adult users, *id.*; and, although the Complaint is littered with photos of ZYN advertisements, Plaintiff fails to identify a single advertisement he relied upon that allegedly induced him to use ZYN and misled him about its properties, *see id.* ¶¶ 5, 90–101. Just like the Plaintiff in *Kelly*, from whom Plaintiff copied his entire Complaint, Plaintiff fails to even specify how he was harmed, apart from a vague assertion of "personal injuries." *Id.* ¶ 7.

Accordingly, like the Complaint in *Kelly*, Plaintiff's Complaint should be dismissed.

II. ARGUMENT

A. The TCA Preempts Plaintiff's Failure-to-Warn and Negligence Claims Concerning ZYN's Labeling and Packaging

The TCA expressly preempts state-law claims that seek to impose "any requirement which is different from, or in addition to," federal requirements "relating to . . . labeling." 21 U.S.C. § 387p(a)(2)(A). This language is "clear and unambiguous" and "sweeps widely" to preempt any

state-labeling requirement that is not *identical* to the FDA-mandated nicotine warning label, with which ZYN fully complies. *In re Fontem US, Inc.*, 2016 WL 6520142, at *2, *4 (C.D. Cal. Nov. 1, 2016); *see* Compl. ¶¶ 2–3, 22, 27, 42. Plaintiff does not and cannot deny that his failure-to-warn and negligence claims assert that ZYN's labeling and packaging fail to provide various warnings, *see* Dkt. 25 ("Mot.") at 6–7; Compl. ¶¶ 63, 84, that are "different from, or in addition to," the FDA-mandated nicotine warning, 21 U.S.C. § 387p(a)(2)(A). Plaintiff's failure-to-warn and negligence claims are therefore expressly preempted.

Plaintiff argues that the TCA's rule of construction, 21 U.S.C. § 387p(b), saves *all* state product-liability claims, Dkt. 27 ("Opp.") at 2, but that interpretation defies the statute's purpose and common sense. The TCA's purpose, among other things, is to "set national standards" regarding tobacco products, Pub. L. No. 111-31, 123 Stat. 1776, 1782 (2009), and to that purpose, the Act establishes uniform labeling requirements. This congressionally-enacted statement of purpose clarifies Congress's intent to preempt all labeling claims to ensure national uniformity. Such a statement "is 'an appropriate guide' to the 'meaning of the statute's operative provisions,'" *Gundy v. United States*, 588 U.S. 128, 142 (2019) (cleaned up), not some mere "policy" argument, as Plaintiff suggests, Opp. at 3. To allow inadequate-labeling claims to evade preemption merely because they are pled as product-liability claims would render the express preemption provision a nullity and subvert Congress's clearly stated purpose. The Court "cannot interpret federal statutes to negate their own stated purposes." *King v. Burwell*, 576 U.S. 473, 493 (2015) (citation omitted).

The cases that Plaintiff cites do not compel a different result. *See* Opp. at 3. Neither of Plaintiff's two primary cases considers the TCA's express purpose. Both concede that the plain text of the TCA requires the "express preemption [of claims] that would require labeling that is 'different from or in addition to' the Nicotine Addictiveness Label Requirement," and both suggest

that product-liability labeling claims can be preempted despite the "savings clause." *See Lara v. Cool Clouds Distrib., Inc.*, 2021 WL 613842, at *9 (D.N.J. Feb. 16, 2021) (citation omitted); *In re JUUL Labs, Inc., Mktg., Sales Pracs., & Prods. Liab. Litig.* 497 F. Supp. 3d 552, 589 (N.D. Cal. 2020) (acknowledging that "labelling claims based on nicotine addiction are preempted"). Early in the *JUUL* litigation, in fact, the court dismissed product-liability labeling claims as preempted. *See Colgate v. JUUL Labs, Inc.* (*Colgate I*), 345 F. Supp. 3d 1178, 1188–89 (N.D. Cal. 2018); *Colgate v. JUUL Labs, Inc.* (*Colgate II*), 402 F. Supp. 3d 728, 751–52 (N.D. Cal. 2019).

Plaintiffs' third case, *R.J. Reynolds Tobacco Co. v. Marotta*, does not interpret the TCA's preemption provision, because the TCA "was enacted in 2009 and does not apply to cases pending before its effective date," including the dispute in *Marotta*. 214 So. 3d 590, 601 (Fla. 2017). Last, Plaintiff's reliance on *Medtronic, Inc. v. Lohr* is misplaced because, unlike the "general federal regulations" that *Medtronic* held not to be preemptive, 518 U.S. 470, 497 (1996), here the FDA has mandated a *specific* labeling requirement, *see Fontem*, 2016 WL 6520142, at *3–4.

Plaintiff's arguments about theoretical failure-to-warn claims that could fall outside of the TCA's preemption provision, s*ee* Opp. at 3–5, are immaterial because Plaintiff's claims do not qualify. Plaintiff's actual failure-to-warn and negligence claims are preempted because they assert that ZYN cans should have had nicotine-related warnings that did not appear. Plaintiff asserts that claims not based on nicotine addiction are not preempted. *Id.* at 4. But all eight of Plaintiff's allegedly omitted warnings address the product's nicotine content or alleged health-impacts from nicotine. *See* Compl. ¶ 63. And the *only* injury Plaintiff alleges from using ZYN is purported harm stemming from nicotine addiction. *See id.* ¶ 7. Similarly, Plaintiff theorizes that claims concerning "false or misleading" labeling are not preempted, Opp. at 4–5, but Plaintiff does not allege that the existing warnings—mandated by FDA—are false; rather he asks the Court to require

additional warnings. Plaintiff's failure-to-warn (Count II) and negligence claims concerning ZYN's labeling and packaging (Count III) are preempted and must be dismissed with prejudice.[1]

B. Plaintiff Fails to Allege a Plausible Failure-to-Warn Claim

Plaintiff's failure-to-warn claim also must be dismissed because Plaintiff does not plausibly plead that (1) ZYN's existing warnings are inadequate or (2) any inadequacy proximately caused his alleged injuries. *See Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. 1st DCA 2009).

First, Plaintiff is wrong that merely listing additional warnings is sufficient to allege that the existing warnings are inadequate; Plaintiff was required to allege *how* the existing, federally-mandated warnings are defective. *See Wright v. Howmedica Osteonics Corp.*, 741 F. App'x 624, 626 (11th Cir. 2018); *Tsavaris v. Pfizer, Inc.*, 2016 WL 375008, at *3 (S.D. Fla. Feb. 1, 2016). Plaintiff asserts that his proposed warnings improve on ZYN's existing warnings but does not explain why that is so. Opp. at 6. A plaintiff could *always* assert that warnings could be phrased differently or more warnings could be given, but that does not mean ZYN's existing warnings are legally inadequate. *Compare, e.g.*, Compl. ¶ 2 (ZYN warning label: "This product contains nicotine. Nicotine is an addictive chemical."), *with id.* ¶ 63(d) (one of Plaintiff's proposed warnings: "Zyn delivers nicotine derived from tobacco"); *see Ferayorni v. Hyundai Motor Co.*, 711 So. 2d 1167, 1172 (Fla. 4th DCA 1998) ("[S]trict liability does not make the manufacturer or

[1] To the extent Plaintiff's product liability and negligence claims relate to ZYN's "advertising and promotion," but do not relate to alleged insufficient warnings on ZYN's label, they would not be preempted. *See* 21 U.S.C. § 387p(a)(2)(B). Here, though, Plaintiff's advertising and promotion claims do relate to allegedly insufficient label warnings. Indeed, Plaintiff is simply trying to circumvent the prohibition on additional warnings on the labels by saying these proffered warnings should be in the advertising and promotion. Congress's intent to have a single, nationwide warning is not so easily elided. In any event, Plaintiff's "advertising and promotion" claims separately fail, as discussed next, because Plaintiff fails to allege why ZYN's existing warnings are inadequate or why different warnings would have caused Plaintiff to abstain from using ZYN.

seller an insurer.").

Plaintiff tries to save his claim by analogizing to the surviving failure-to-warn claims in the *JUUL* case. He asserts that, similar to the JUUL device, "nicotine pouches like Zyn are relatively new, and the dangers associated with such products are not obvious." Opp. at 7. But the claims in *JUUL* did not turn on the device's novelty, but rather specific allegations of misrepresentations regarding the device's nicotine delivery: namely, that JUUL (1) marketed its product as delivering approximately 25% less nicotine than a cigarette and (2) failed to warn that its product in fact delivered about 30% more nicotine per puff than a traditional cigarette and was stronger than advertised. *Colgate II*, 402 F. Supp. 3d at 739, 751. Here, Plaintiff does not allege that ZYN contains or delivers a different amount of nicotine than advertised. To the contrary, ZYN expressly discloses that it contains particular amounts of nicotine and that it is addictive.

Second, Plaintiff fails to plausibly allege that the supposedly inadequate warnings proximately caused him to use ZYN. For example, in addition to ZYN's FDA-mandated warning that it contains nicotine, Plaintiff contends that ZYN should warn that it "delivers nicotine derived from tobacco." Compl. ¶ 63(d). But Plaintiff provides no explanation of why or how a warning that the nicotine in ZYN is derived from tobacco would have deterred him from using it when a warning that it contains nicotine, an addictive chemical, did not. Plaintiff cannot simply assert that "if [he] had been given adequate warnings and instructions, he would not have used Zyn." Opp. at 9. That is a mere "legal conclusion couched as a factual allegation" that should be dismissed even if it were not preempted. *See Edwards v. Dothan City Schs.*, 82 F.4th 1306, 1310 (11th Cir. 2023) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

C. Plaintiff Fails to Allege a Plausible Design-Defect Claim

1. The Consumer Expectations Test

Plaintiff fails to state a claim under the consumer expectations test because he cannot

plausibly allege that ZYN "failed to perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner." *See Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 503 (Fla. 2015). Plaintiff argues that ZYN failed to meet consumer expectations because it "delivers a potent amount of nicotine," which is addictive and may cause harmful effects. Opp. at 10 (citing Compl. ¶¶ 20, 51). But ZYN comes with a prominent warning that it includes addictive nicotine. *See* Compl. ¶ 2. ZYN purchasers also know exactly the amount of nicotine in the pouches they are purchasing because that information is prominently displayed on ZYN's label. *See id*. Plaintiff has not set forth any plausible allegations that ordinary consumers exposed to this information expected ZYN to contain either no nicotine or a different amount of nicotine than stated on the package. *See Cates v. Zeltiq Aesthetics, Inc.*, 73 F.4th 1342, 1353 (11th Cir. 2023) (quoting *Aubin*, 177 So. 3d at 507) ("The consumer expectations test intrinsically recognizes a manufacturer's central role in crafting the image of a product and establishing the consumers' expectations for that product.").

Plaintiff cites the *JUUL* court's refusal to dismiss a design-defect claim, but *JUUL* highlights the deficiencies in Plaintiff's Complaint. The alleged design defect in *JUUL* was that JUUL's products "contain[ed] more nicotine than users expect[ed]." Opp. at 11 (quoting *Colgate I*, 345 F. Supp. 3d at 1193). In particular, although the packaging of JUUL's pods stated that they contained "5% nicotine," the pods allegedly "contain[ed] 6.2% nicotine salt, rather than the 5% nicotine advertised" on the packaging. *Colgate I*, 345 F. Supp. 3d at 1193. That difference created a mismatch between the consumer's expectation and what the consumer received. Here, by contrast, Plaintiff does not allege that ZYN contains more nicotine than disclosed on its packaging.

Plaintiff's reliance on *McCracken v. R.J. Reynolds Tobacco Co.* is also misplaced. *See* Opp. at 11. *McCracken* applied a "less stringent standard[]" to a pro se complaint, and permitted

a design-defect claim to proceed based on an allegation that the manufacturers had deliberately "alter[ed] the amount of nicotine to encourage continued addiction." 2018 WL 2304041, at *2, *6 (E.D. Pa. May 21, 2018). Plaintiff here is not pro se and does not allege that the nicotine in ZYN has been altered to make it more addictive. Plaintiff points to a vague, bald assertion that ZYN was designed "with a pharmacokinetic profile engineered to create risks of abuse and addiction." Opp. at 11 (citing Compl. ¶ 49). Even read liberally, that allegation says nothing more than that ZYN contains an addictive substance—precisely what ZYN warns on its label.

2. The Risk-Utility Test

Plaintiff's design-defect allegations also fail under a risk-utility theory. Plaintiff asserts that ZYN is defectively designed "because it delivers a potent amount of nicotine and it is designed to create and sustain an addiction." Opp. at 12. But ZYN's label discloses the amount of nicotine per pouch, and it warns that nicotine is addictive. *See* Compl. ¶¶ 2, 19. The fact that ZYN contains the nicotine content prominently disclosed on its label does not render the product defective.

Plaintiff also argues that ZYN is defectively designed "because it include[s] features making the product attractive and more palatable to youth and non-smokers," such as flavors. Opp. at 12 (quoting Compl. ¶ 50). It is not a design defect to add a feature like flavors that appeals to lawful adult users, even if it might also appeal to unlawful underage users. Binding Eleventh Circuit authority allows a defendant to be held strictly liable for a design defect "only when the product is used as intended," and the "intended use" of a product under Florida law does not include "unintended uses." *Jennings v. BIC Corp.*, 181 F.3d 1250, 1256 (11th Cir. 1999) (citing *High v. Westinghouse Elec. Corp.*, 610 So. 2d 1259, 1262 (Fla. 1992)). Plaintiff does not dispute that ZYN is an age-restricted product, and Plaintiff alleges he began using it "under the age of 20." Compl. ¶ 6. Plaintiff instead argues that *Jennings* was wrongly decided. But he points to no authority that the Court may ignore the Eleventh Circuit's interpretation of Florida law. In fact,

his own citation makes clear that a circuit court's interpretation of state law is binding on district courts, unless "a *later* decision by the state appellate court cast[s] doubt" on the Circuit's "interpretation of that law." Opp. at 13 (emphasis added) (quoting *EmbroidMe.com, Inc. v. Travelers Prop. Cas. Co. of Am.*, 845 F.3d 1099, 1105 (11th Cir. 2017)). The only case Plaintiff identifies, *Standard Havens Prods., Inc. v. Benitez*, 648 So. 2d 1192 (Fla. 1994), concerned a negligence claim—not strict liability—and was issued before *Jennings*. *See id.*

Nor can Plaintiff make out a design-defect claim on the theory that a product must be designed to deter use—*e.g.*, by using unpalatable flavors. Plaintiff cites no authority holding that a manufacturer must make a product less attractive for its intended use to deter unintended uses. Plaintiff's allegation that ZYN includes features that attract youth does not state a design defect.

3. Plaintiff Fails to Plausibly Plead Causation

Plaintiff's design-defect claim independently fails because he does not plausibly plead that any design defect proximately caused his asserted injuries. As with the failure-to-warn claim, the Complaint simply recites the legal standard, which is insufficient. *See* Compl. ¶ 57; *Sparks v. Medtronic, Inc.*, 2021 WL 2649235, at *2 (M.D. Fla. June 28, 2021). Plaintiff argues that courts have permitted such conclusory causation allegations, Opp. at 15, but the cases he cites involved far more detailed causation allegations, including identifying specific injuries resulting from the alleged defect. *See Hicks v. Bombardier Recreational Prods. Inc.*, 684 F. Supp. 3d 1223, 1244 (S.D. Fla. 2023) (listing specific injuries); *Milana v. Eisai, Inc.*, 2022 WL 846933, at *8 (M.D. Fla. Mar. 22, 2022) (breast cancer). Here, Plaintiff simply alleges he is addicted to nicotine—the very harm warned of—and has suffered unspecified "personal injuries," Compl. ¶ 7, without any facts to support an inference that some alleged defect proximately caused his unidentified injuries.

D. Plaintiff Fails to Allege a Plausible Negligence Claim

Plaintiff's negligence claim is preempted, and in any event must be dismissed because it is

subsumed by his strict product liability claim. *See Colgate II*, 402 F. Supp. 3d at 752.

E. Plaintiff Fails to Plead Fraud with Particularity

Plaintiff's fraud claim does not allege "the who, what, when, where, and how of the fraud alleged." *Omnipol, A.S. v. Multinational Def. Servs., LLC*, 32 F.4th 1298, 1307 (11th Cir. 2022). Plaintiff largely concedes that he has not pled affirmative misrepresentations with the requisite specificity. Although he argues that the Complaint "specifically references Defendants' statement that ZYN is 'tobacco free,'" the Complaint does not allege whether Plaintiff saw this statement, where and when he saw it, or whether or how he relied on it. Opp. at 17 (citing Compl. ¶ 93). Plaintiff's allegations of affirmative fraud fall far short of Rule 9(b)'s requirements. *See Omnipol*, 32 F.4th at 1307; *see also Colgate I*, 345 F. Supp. 3d at 1191 (dismissing fraud claims that "failed to specifically identify" the advertisements the plaintiffs saw).

Plaintiff focuses instead on alleged fraudulent omissions and asserts that claims based on omissions need not be pleaded with the same level of specificity. *See* Opp. at 17. Plaintiff is wrong. Rule 9(b) "applies equally to frauds based on affirmative misstatements and misleading omissions." *Durden v. Citicorp Tr. Bank, FSB*, 2008 WL 2098040, at *6 (M.D. Fla. May 16, 2008); *accord Koski v. Carrier Corp.*, 347 F. Supp. 3d 1185, 1196 (S.D. Fla. 2017). The authorities on which Plaintiff relies—two unpublished, out-of-district cases—are inapposite: one relies on inapplicable law, *see Hadjian v. Mercedes-Benz, USA, LLC*, 2022 WL 3699603, at *8 (N.D. Ga. Mar. 31, 2022) (citing Ninth Circuit case law), while the other still required the plaintiff to plead "the who, what, when, where, and how," *see Nalley v. Gen. Motors LLC*, 2022 WL 18459646, at *5 (N.D. Ga. Aug. 30, 2022).

A claim based on fraudulent omissions still must precisely identify the alleged omissions, the time and place of such omissions, and the manner in which the alleged omissions were misleading. *Durden*, 2008 WL 2098040, at *6. Plaintiff fails to identify any advertising he

viewed, what information was allegedly omitted from that advertising to render it misleading by omission, "where" or "when" he saw it, or how he relied on the allegedly misleading-by-omission advertising. For example, Plaintiff asserts that he was generally "influenced by Zyn's marketing and advertising," and so "the 'when' is from when Plaintiff began using Zyn through the present." Opp. at 17. But Plaintiff cannot meet Rule 9(b)'s requirements by "[s]imply referring to the Defendants' advertisements" without referencing a "time and date . . . [or] specific place." *Quashie v. Olympus Am., Inc.*, 315 F. Supp. 3d 1329, 1340–41 (N.D. Ga. 2018) (dismissing fraudulent concealment in advertising claim); *see also Jovine v. Abbott Lab'ys, Inc.*, 795 F. Supp. 2d 1331, 1343 n.9 (S.D. Fla. 2011). Even where the fraud allegedly "occurred repeatedly on different days and times," the plaintiff "should still be able to document specific days and times that those misrepresentations occurred." *NCR Credit Corp. v. Reptron Elecs., Inc.*, 155 F.R.D. 690, 693 (M.D. Fla. 1994). Because Plaintiff did not do so, the fraud claim should be dismissed.

F. Plaintiff Fails to Allege Entitlement to Medical Monitoring

Plaintiff's request for medical monitoring is not pleaded as a cause of action, and fails for that reason alone. *See, e.g.*, *Jerue v. Drummond Co., Inc.*, 2017 WL 10876737, at *14 (M.D. Fla. Aug. 17, 2017). Beyond that, the Complaint comes nowhere near pleading the required elements. Plaintiff asserts that he "satisfies the first four requirements" and that the "remaining three requirements can be reasonably inferred." Opp. at 20. But it is Plaintiff's burden to "establish" the elements, and the opposition fails to identify anything in the Complaint that would allow the Court to even "infer" an adequately pled medical monitoring claim. *Garrett-Alfred v. Facebook, Inc.*, 540 F. Supp. 3d 1129, 1143 (M.D. Fla. 2021) (dismissing medical monitoring claim that did not allege all the elements, such as "that screening for these [] injuries is different" than routine).

III. CONCLUSION

Plaintiff's Complaint should be dismissed.

Dated: June 24, 2024

Respectfully submitted,

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I hereby certify that on this 24th day of June 2024, I electronically filed the foregoing with the Clerk of Court using CM/ECF. I also certify that the foregoing document is being served this day on the counsel of record or pro se parties on the Service List below via transmission of Notices of Electronic Filing generated by CM/ECF.

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